FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

April 5, 2017

UNITED PARCEL SERVICE
Delivery Signature Requested

Reginald Dilliard, D.Ph.
Executive Director
Tennessee Board of Pharmacy
665 Mainstream Drive
Nashville, Tennessee 37243

RE: FDA Inspection of Mooney's Pharmacy, Inc.

Dear Dr. Dilliard:

The purpose of this letter is to refer to the Tennessee Board of Pharmacy (BOP) for appropriate follow-up, the U.S. Food and Drug Administration's (FDA) concerns about poor practices observed during an FDA inspection at a pharmacy licensed by the Tennessee BOP, Mooney's Pharmacy, Inc., 1107 North Roan Street, Johnson City, Tennessee. (Pharmacy License #00001663).

FDA inspected the firm from August 29 to September 2, 2016. The FDA investigator was accompanied by a Tennessee Board of Pharmacy state investigator on the first day of the inspection (one day). A redacted copy of a Form FDA 483 which documents our investigator's observations from the inspection can be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm520200.pdf

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Mooney's Pharmacy, Inc., and determined, based on this sample, the firm appears to obtain valid prescriptions for individually-identified patients for the drug products which it compounds and distributes.

During the inspection, the FDA investigator observed deviations that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. For example, our investigator observed beta-lactam and hazardous drugs were produced without adequate containment or cleaning of work surfaces to prevent cross-contamination. In addition, stains were observed on the ceiling of the compounding room directly above the work bench as well as on the carpet in the compounding room.

U.S. Food and Drug Administration
404 BNA Drive
Building 200 – Suite 500
Nashville, TN 37217

Telephone: (615) 366-7801
FAX: (615) 366-7802
www.fda.gov

Mooney's Pharmacy, Inc., committed to FDA in its written responses, received on September 15 and November 22, 2016, to correct the deviations in the Form FDA 483. In addition, the deviations identified appear to be readily correctable.

After review of the records, FDA does not currently intend to take further action on the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients and FDA believes the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Tennessee BOP for follow-up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with human or animal drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

For reporting animal adverse drug events, please follow the link to the FORM FDA 1932a found at: http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Rebecca Asente, Compliance Officer, at 504-846-6104, or by email at Rebecca.Asente@fda.hhs.gov.

Sincerely,

Ruth Dixon
District Director
New Orleans District Office